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**DEPARTMENT OF JUSTICE
Drug Enforcement Administration
[Docket No. DEA-365]**

Final Adjusted Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2013

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Notice.

SUMMARY: This notice establishes final adjusted 2013 aggregate production quotas for controlled substances in Schedules I and II of the Controlled Substances Act (CSA) and assessment of annual needs for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, as well as the 2013 aggregate production quotas for three recently temporarily controlled substances.

FOR FURTHER INFORMATION CONTACT: John W. Partridge, Executive Assistant, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152, Telephone: (202) 307-7165.

SUPPLEMENTARY INFORMATION:

Background

Section 306 of the CSA (21 U.S.C. 826) requires the Attorney General to establish aggregate production quotas for each basic class of controlled substance listed in Schedules I and II and for ephedrine, pseudoephedrine, and phenylpropanolamine. This responsibility has been delegated to the Administrator of the DEA through 28 CFR 0.100. The Administrator, in turn, has redelegated this function to the Deputy Administrator, pursuant to 28 CFR 0.104. DEA published the 2013 established aggregate

production quotas for controlled substances in Schedules I and II and assessment of annual needs for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine in the Federal Register (77 FR 59980) on October 1, 2012. That notice stated that the Deputy Administrator would adjust, as needed, the established aggregate production quotas in 2013 as provided for in 21 CFR 1303.13 and 21 CFR 1315.13. The 2013 proposed adjusted aggregate production quotas for controlled substances in Schedules I and II and assessment of annual needs for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine were subsequently published in the Federal Register on June 20, 2013, (78 FR 37237) in consideration of the outlined criteria. All interested persons were invited to comment on or object to the proposed adjusted aggregate production quotas and assessment of annual needs on or before July 22, 2013.

Analysis for Final Adjusted 2013 Aggregate Production Quotas and Assessment of Annual Needs

Consideration has been given to the criteria outlined in the June 20, 2013, notice of proposed adjusted aggregate production quotas and assessment of annual needs, in accordance with 21 CFR 1303.13 and 21 CFR 1315.13. Six companies submitted timely comments regarding a total of 30 Schedule I and II controlled substances. Comments received proposed that the aggregate production quotas for 2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (2C-P); 2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E); 2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D); 2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N); 2-(2,5-Dimethoxyphenyl)ethanamine (2C-H); 2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C); 2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine

(2C-I); 2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-2); 2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-4); 3,4-Methylenedioxyamphetamine (MDMA); 4-Anilino-N-phenethyl-4-piperidine (ANPP); amphetamine (for sale); codeine (for conversion); dihydromorphine; diphenoxylate (for sale); gamma hydroxybutyric acid; hydrocodone; hydromorphone; levomethorphan; methadone; methadone intermediate; methylphenidate; morphine (for conversion); morphine (for sale); oxycodone (for sale); oripavine; oxymorphone (for conversion); oxymorphone (for sale); phenylacetone; and sufentanil were insufficient to provide for the estimated medical, scientific, research, and industrial needs of the United States, for export requirements, and for the establishment and maintenance of reserve stocks. One manufacturer commented that the APQ for thebaine was insufficient; however, that commenter was referring to a need for procurement quota for thebaine, which does not directly impact the APQ and, thus, was not considered. DEA did not previously propose adjustments to the 2013 assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine and received no comments concerning such.

DEA has taken into consideration the above comments along with the relevant 2012 year-end inventories, initial 2013 manufacturing quotas and import quotas, 2013 export requirements, actual and projected 2013 sales, research and product development requirements, and additional applications received. Based on all of the above, the Deputy Administrator has determined that the proposed adjusted 2013 aggregate production quotas and assessment of annual needs for dihydromorphine; diphenoxylate (for sale); gamma hydroxybutyric acid; hydromorphone; levomethorphan; morphine (for sale); oxymorphone (for sale); phenylacetone; psilocyn; sufentanil; ephedrine (for sale);

phenylpropanolamine (for conversion); and pseudoephedrine (for sale) required additional consideration and hereby further adjusts the 2013 aggregate production quotas for those substances.

Regarding 2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (2C-P); 2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E); 2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D); 2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N); 2-(2,5-Dimethoxyphenyl)ethanamine (2C-H); 2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C); 2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I); 2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-2); 2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-4); 3,4-Methylenedioxymethamphetamine (MDMA); 4-Anilino-N-phenethyl-4-piperidine (ANPP); amphetamine (for sale); codeine (for conversion); hydrocodone; methadone; methadone intermediate; methylphenidate; morphine (for conversion); oxycodone (for sale); oripavine; and oxymorphone (for conversion), the Deputy Administrator hereby determines that the proposed adjusted 2013 aggregate production quotas and assessment of annual needs for these substances and List I chemicals as published on June 20, 2013, (78 FR 37237) are sufficient to meet the current 2013 estimated medical, scientific, research, and industrial needs of the United States and to provide for adequate inventories.

As described in the previously published notice establishing the 2013 aggregate production quotas and assessment of annual needs, DEA has specifically considered that inventory allowances granted to individual manufacturers may not always result in the availability of sufficient quantities to maintain an adequate reserve stock pursuant to 21 U.S.C. 826(a), as intended. See 21 CFR 1303.24. This would be concerning if a natural

disaster or other unforeseen event resulted in substantial disruption to the amount of controlled substances available to provide for legitimate public need. As such, DEA has included in all proposed revised Schedule II aggregate production quotas, and certain Schedule I aggregate production quotas, an additional 25% of the estimated medical, scientific, and research needs as part of the amount necessary to ensure the establishment and maintenance of reserve stocks. The resulting adjusted established aggregate production quotas will reflect these included amounts. This action will not affect the ability of manufacturers to maintain inventory allowances as specified by regulation. DEA expects that maintaining this reserve in certain established aggregate production quotas will mitigate adverse public effects if an unforeseen event resulted in substantial disruption to the amount of controlled substances available to provide for legitimate public need, as determined by DEA. DEA does not anticipate utilizing the reserve in the absence of these circumstances.

Pursuant to the above, the Deputy Administrator hereby finalizes the 2013 aggregate production quotas for the following Schedule I and II controlled substances and the 2013 assessment of annual needs for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in grams of anhydrous acid or base, as follows:

Basic Class	Final Adjusted 2013 Quotas
Temporarily Scheduled Substances	
(1-Pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144)	15 g
[1-(5-fluoro-pentyl)-1H-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (XLR11)	15 g
N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide (AKB48)	15 g
Schedule I	
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	45 g

1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	45 g
1-[1-(2-Thienyl)cyclohexyl]piperidine	5 g
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200)	45 g
1-Butyl-3-(1-naphthoyl)indole (JWH-073)	45 g
1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR-18 and RCS-8)	45 g
1-Hexyl-3-(1-naphthoyl)indole (JWH-019)	45 g
1-Methyl-4-phenyl-4-propionoxypiperidine	2 g
1-Pentyl-3-(1-naphthoyl)indole (JWH-018 and AM678)	45 g
1-Pentyl-3-(2-chlorophenylacetyl)indole (JWH-203)	45 g
1-Pentyl-3-(2-methoxyphenylacetyl)indole (JWH-250)	45 g
1-Pentyl-3-(4-chloro-1-naphthoyl)indole (JWH-398)	45 g
1-Pentyl-3-(4-methyl-1-naphthoyl)indole (JWH-122)	45 g
1-Pentyl-3-[(4-methoxy)-benzoyl]indole (SR-19, RCS-4)	45 g
1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH-081)	45 g
2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (2C-P)	15 g
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E)	15 g
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D)	15 g
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N)	15 g
2-(2,5-Dimethoxyphenyl)ethanamine (2C-H)	15 g
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C)	15 g
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I)	15 g
2,5-Dimethoxy-4-ethylamphetamine (DOET)	12 g
2,5-Dimethoxy-4-n-propylthiophenethylamine	12 g
2,5-Dimethoxyamphetamine	12 g
2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-2)	15 g
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-4)	15 g
3,4,5-Trimethoxyamphetamine	12 g
3,4-Methylenedioxyamphetamine (MDA)	30 g
3,4-Methylenedioxymethamphetamine (MDMA)	50 g
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	24 g
3,4-Methylenedioxy-N-methylcathinone (methylone)	35 g
3,4-Methylenedioxypropylvalerone (MDPV)	25 g
3-Methylfentanyl	2 g
3-Methylthiofentanyl	2 g
4-Bromo-2,5-dimethoxyamphetamine (DOB)	12 g
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	12 g
4-Methoxyamphetamine	88 g
4-Methyl-2,5-dimethoxyamphetamine (DOM)	25 g
4-Methylaminorex	12 g

4-Methyl-N-methylcathinone (mephedrone)	25 g
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	68 g
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47, 497 C8-homolog)	53 g
5-Methoxy-3,4-methylenedioxyamphetamine	12 g
5-Methoxy-N,N-diisopropyltryptamine	12 g
5-Methoxy-N,N-dimethyltryptamine	10 g
Acetyl-alpha-methylfentanyl	2 g
Acetyldihydrocodeine	2 g
Acetylmethadol	2 g
Allylprodine	2 g
Alphacetylmethadol	2 g
Alpha-ethyltryptamine	12 g
Alphameprodine	2 g
Alphamethadol	2 g
Alpha-methylfentanyl	2 g
Alpha-methylthiofentanyl	2 g
Alpha-methyltryptamine (AMT)	12 g
Aminorex	12 g
Benzylmorphine	2 g
Betacetylmethadol	2 g
Beta-hydroxy-3-methylfentanyl	2 g
Beta-hydroxyfentanyl	2 g
Betameprodine	2 g
Betamethadol	2 g
Betaprodine	2 g
Bufotenine	3 g
Cathinone	12 g
Codeine-N-oxide	602 g
Desomorphine	5 g
Diethyltryptamine	12 g
Difenoxin	50 g
Dihydromorphine	3,990,000 g
Dimethyltryptamine	18 g
Gamma-hydroxybutyric acid	67,500,000 g
Heroin	25 g
Hydromorphenol	54 g
Hydroxypethidine	2 g
Ibogaine	5 g

Lysergic acid diethylamide (LSD)	30 g
Marihuana	21,000 g
Mescaline	13 g
Methaqualone	10 g
Methcathinone	14 g
Methyldihydromorphine	2 g
Morphine-N-oxide	655 g
N,N-Dimethylamphetamine	12 g
N-Benzylpiperazine	15 g
N-Ethylamphetamine	12 g
N-Hydroxy-3,4-methylenedioxyamphetamine	12 g
Noracymethadol	2 g
Norlevorphanol	52 g
Normethadone	2 g
Normorphine	18 g
Para-fluorofentanyl	2 g
Phenomorphan	2 g
Pholcodine	2 g
Properidine	2 g
Psilocybin	10 g
Psilocyn	12 g
Tetrahydrocannabinols	491,000 g
Thiofentanyl	2 g
Tilidine	10 g
Trimeperidine	2 g
Schedule II	
1-Phenylcyclohexylamine	3 g
1-Piperdinocyclohexanecarbonitrile	21 g
4-Anilino-N-phenethyl-4-piperidine (ANPP)	2,250,000 g
Alfentanil	38,250 g
Alphaprodine	3 g
Amobarbital	9 g
Amphetamine (for conversion)	22,875,000 g
Amphetamine (for sale)	47,186,000 g
Carfentanil	6 g
Cocaine	240,000 g
Codeine (for conversion)	81,250,000 g
Codeine (for sale)	49,506,250 g
Dextropropoxyphene	19 g
Dihydrocodeine	250,000 g

Diphenoxylate	887,500 g
Ecgonine	144,000 g
Ethylmorphine	3 g
Fentanyl	2,108,750 g
Glutethimide	3 g
Hydrocodone (for sale)	99,625,000 g
Hydromorphone	6,750,000 g
Isomethadone	5 g
Levo-alphaacetylmethadol (LAAM)	4 g
Levomethorphan	195 g
Levorphanol	4,500 g
Lisdexamfetamine	21,000,000 g
Meperidine	6,875,000 g
Meperidine Intermediate-A	6 g
Meperidine Intermediate-B	11 g
Meperidine Intermediate-C	6 g
Metazocine	6 g
Methadone (for sale)	33,125,000 g
Methadone Intermediate	40,500,000 g
Methamphetamine	3,912,500 g
[987,500 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 2,863,750 grams for methamphetamine mostly for conversion to a schedule III product; and 61,250 grams for methamphetamine (for sale)]	
Methylphenidate	96,750,000 g
Morphine (for conversion)	91,250,000 g
Morphine (for sale)	61,125,000 g
Nabilone	25,628 g
Noroxymorphone (for conversion)	9,000,000 g
Noroxymorphone (for sale)	1,262,500 g
Opium (powder)	91,250 g
Opium (tincture)	1,287,500 g
Oripavine	22,750,000 g
Oxycodone (for conversion)	10,250,000 g
Oxycodone (for sale)	153,750,000 g
Oxymorphone (for conversion)	18,375,000 g
Oxymorphone (for sale)	7,000,000 g
Pentobarbital	42,500,000 g
Phenazocine	6 g
Phencyclidine	30 g
Phenmetrazine	3 g

Phenylacetone	42,393,750 g
Racemethorphan	3 g
Remifentanyl	3,750 g
Secobarbital	215,003 g
Sufentanyl	6,880 g
Tapentadol	13,750,000 g
Thebaine	145,000,000 g
List I Chemicals	
Ephedrine (for conversion)	15,100,000 g
Ephedrine (for sale)	4,200,000 g
Phenylpropanolamine (for conversion)	44,800,000 g
Phenylpropanolamine (for sale)	6,100,000 g
Pseudoephedrine (for sale)	246,000,000 g

Aggregate production quotas for all other Schedule I and II controlled substances included in 21 CFR 1308.11 and 1308.12 remain at zero.

Dated: August 1, 2013

Thomas M. Harrigan
Deputy Administrator

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